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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,577	06/28/2001	Shigefumi Sakai	210354US0	2545

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/892,577

Applicant(s)

SAKAI ET AL.

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 33-49 and 51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-49 and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt is acknowledged of supplement amendment filed on September 16, 2005. Claims 33-49 and 51 are pending. Claim rejection made under 35 U.S.C. § 112, second paragraph, as indicated in the previous Office action dated February 25, 2005, is withdrawn in view of applicants' remarks. Claim rejections made under 35 U.S.C. §§ 102 and 103 as indicated in the same Office action are withdrawn in view of claim amendments made by applicants. New rejections are made.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 33-43, 46-49, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Delrieu et al. (US 5961990) ("Delrieu") in view of Noda et al. (US 5089269) in view of Noda et al. (US 5089269) ("Noda") and Rosentreich et al. (US 3932609) ("Rosentrieck").**

The present claims are product-by-process claims. The court in In re Thorpe held, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted). The court in In re Brown also held, "when the prior art discloses a product which reasonably appears to

be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable.” See 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). The requirement for the physical property limitation of the composition here means that the prior art composition should comprise hydrogel particles comprising a non-crosslinked hydrogel having an oil component dispersed therein, wherein the hydrogel particles are dispersed in an aqueous medium. The limitations in the dependent claims that are directed to the physical properties of the hydrogel particles, such as droplet shape and size, breaking intensity, ratio of longest/shortest diameters, etc. will be also considered. See instant claims 37, 39-49. However, the limitation on the process of making the claimed hydrogel-containing composition as recited in the base claim, Claim 33, is directed to the process of making the composition which is viewed not patentably distinct from the prior art cited herein. Although examiner has not given weight to the process limitations in Claims 33-36, and 38, the prior art method of making hydrogel particles is discussed below.

Delrieu teaches agar gel beads of an average diameter of 2 mm comprising lipophilic beta-carotene dispersed in water. See Example 7; instant claims 33, 39, 40, and 46. The reference teaches that the particles are formed by injecting the agar solution/beta-carotene mixture through a needle into liquid paraffin oil at 5 °C, a temperature below the agar gelling point. See instant claim 38. See col. 4, line 62 – col. 5, line 18 for the method of making the beads. The resulting agar beads are then incorporated into cosmetic compositions such as creams, gels and lotions (an aqueous

composition). See col. 16, lines 53 – 58; instant claim 49. While the applications of vibration to the apparatus as recited in instant claims 34-36 are process limitations, it is nevertheless noted that Delrieu teaches to control the size of the beads by agitation of the oil bath. Col. 13, line 65 – col. 14, line 6; Example 10. See instant claims 33, 34-36. The reference teaches restraining polymers that are dispersed in the agar gel, which is viewed as polymer emulsifying-dispersing agents, which include quaternized polysaccharides. See col. 4, lines 6 – 20; col. 8, line 18 – col. 10, line 5. See instant claims 41 and 43. The reference teaches that at least 80 % of the particles are within the desired average particle size range of 0.05-10 mm. See col. 5, lines 42 – 59.

As for claims 47 and 48, it is well settled in patent law that if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present since a chemical composition and its properties are inseparable. See In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prior art agar beads that meet the claimed limitations of instant claim 33 necessarily has the same breaking intensity and gel strength of the gel bead as recited in claims 47 and 48, respectively. See also col. 13, lines 7 – 26 which teaches that the hardness of the gel beads are controlled so that the beads are soft and crushable upon contact with the skin.

Delrieu fails to teach the viscosity and the specific gravity of the aqueous medium of the composition.

Noda teaches skin cosmetics such as lotions which contain oily components and emulsifiers enclosed in gelatin microcapsules in the aqueous phase. See Examples 3-1

through 3-7. The gelatin capsules in Noda are considered to be “non-crosslinked hydrogel” as applicants define in instant specification p. 5, lines 21 – p. 6, line1, since the gel in Noda is formed by dissolving the gelatin in heated water and cooling. See Noda, Example 3-1. See also col. 8, lines 45 – 51 for suitable water-soluble polymers including agar. Noda further teaches that the viscosity of the compositions ranges from 1,000 to 20,000 cps (1000 –200,000 mPa.s), which is within the claimed range in the instant claim 17. See col. 5, lines 56 – 63. While the reference lacks the teaching of the specific gravity of the composition, it teaches of a surfactant solution containing capsules with improved dispersity by adjustment of the specific gravity. See col. 3, lines 40 – 45. Based on this disclosure in Noda, examiner views that a routineer would have discovered the optimal range of the specific gravity of the aqueous medium of the instant invention by routine experimentation.

Rosentreich et al. teach stable antiperspirant liquid compositions. The reference teaches the preferred viscosity range for the lotion formulation is 500-2225 cps (500-2225 mPa.s) at ambient temperature, while the specific gravity is 1.100-1400. See col. 4, lines 21 – 29.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Delrieu by adjusting the viscosity and specific gravity of the aqueous medium of the composition as motivated by Noda and Rosentreich because 1) Noda teaches the acceptable viscosity range of a cosmetic such as lotion which contains agar beads; and further teaches that adjust specific gravity of a solution can improve the dispersity of capsules in the composition;

2) Rosentreich teach the preferred viscosity and specific gravity for an aqueous lotion composition. The skilled artisan would have had a reasonable expectation of successfully producing a cosmetic composition having topically acceptable viscosity and good dispersity of the agar beads by combining the teachings of the references.

**Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delrieu, Noda, and Rosentreich as applied to claims 33-43, 46-49, and 51 as above, and further in view of Tsaaur et al. (US 5726138).**

While Delrieu, discussed above, teaches dermatological actives suitable for the invention in col. 10, lines 6 – col. 11, line 11, the reference fails to teach solid fatty actives or ceramides.

Tsaaur discloses aqueous compositions comprising hydrogel particles comprising water-insoluble skin benefit ingredients entrapped therein. See col. 2, line 63 – col. 3, line 60. Tsaaur teaches that the suitable benefit agents include specific waxes, hydrocarbons, cholesterol ester ceramides, and pseudoceramides. See col. 8, lines 5 – 58; Examples 8-10; see instant claims 44 and 45. These actives are taught to provide protection, moisture or conditioning effect to the skin. See *Id.* The reference teaches that the benefit agent is dispersed in the hydrogel-forming polymers before the formation into hydrogel particles. See col. 4, lines 28 – 44; instant claim 41. Using surfactants in mixing the benefit agent and the hydrogel-forming polymer solution is also disclosed in col. 9, lines 6 – 24. See instant claim 41. The reference teaches using acrylic polymers such as modified polysaccharides, cationic modified cellulose,

Carbopol by B.F. Goodrich, polyvinyl alcohol, which meet the “polymer emulsifying or dispersing agent” limitation of instant claim 43. See col. 7, lines 48-65. It is also noted that modified polysaccharides and cationic modified cellulose are used in Delrieu as restraining polymers. The reference teaches an aqueous lotion composition with petrolatum, a solid fatty substance with m.p. 38-60°C, contained in a hydrogel particle comprising chitosan, a non-crosslinked, thermal gelatin. See Example 15; instant claims 42, 44, and 49. The diameter of the petrolatum hydrogel particles there is deemed to be 200 microns. See instant claim 37. Tsaur teaches using two types of polymers to form hydrogel, wherein the first polymer may be thermal gelatin, such as agar or gelatins; and the second polymer is selected depending on the desired gel strength. See col. 5, line 56 – col. 6, line 22; instant claim 47. The reference further teaches that the gel strength can be manipulated by controlling the amounts of the two polymers and the particle size. See col. 7, lines 33 – 40; col. 17, lines 44 – 57; instant claim 47.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions comprising agar beads of Delrieu by substituting the actives with the Tsaur wax or ceramides along with surfactants, as motivated by the collective teachings of the references, because 1) Delrieu teaches using dermatologically active substances to provide prophylactic and treatment effect to the skin; and 2) Tsaur teaches that the disclosed benefit agents therein can protect, moisturize or condition the skin after being deposited from the aqueous composition.



The skilled artisan would have had a reasonable expectation of successfully producing a cosmetic composition which provides the controlled-release of the cosmetic wax or ceramide active ingredients because both Delrieu and Tsaur are teach hydrogel particles comprising oily active ingredients dispersed therein which are then incorporated into aqueous medium.

### ***Response to Arguments***

Applicant's arguments with respect to claims 33-49 and 51 have been considered but are moot in view of the new ground(s) of rejection in part, and unpersuasive in part.

Applicants' arguments with respect to the new claim limitations are moot in view of the new grounds of rejection as discussed above.

In response to applicants' argument that Delrieu fails to teach the application of vibration during the discharging of hydrogel particles, examiner reiterates that only the products and not the process of making thereof are given patentable weight in this case. It is true that the structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). Applicants assert that the vibration process steps make it possible to control "shape and/or uniformity" of the particles, which is directed to the structure of the product. It is noted that applicants disclose in specification, p. 16, lines 3-16 that the vibration technique affects the production

efficiency and uniformity in size of the particles, rather than the shape of the particles. Nonetheless, the resulting hydrogel particles from the applicants' method do not have structural characteristic that are "distinctive" from the agar beads of Delrieu because the prior art hydrogel particles are also said to be spherical and uniform in size. The agitation of oil bath may be a different technique from the claimed invention, but the prior art method also results in the same product. Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In *re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). In this case, examiner takes the position that the rejection is proper since the evidence of the record shows that the agar beads in Delrieu are same or similar to applicants' hydrogel particles. The burden is on applicants' to show that the presently claimed hydrogel particles are patentably distinct from the prior art.

Applicants also argue that Tsaur is not combinable with Delrieu because the reference is directed to producing irregular shaped particles. In response to applicant's argument that Tsaur is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Tsaur is concerned with delivering skin

benefit agents to the skin, which is the field of applicants' endeavor. Examiner notes that the reference is used to show that it would have been obvious to use solid fat as a moisturizing agent. The combined references do not provide any teaching or suggestion, either expressly or implicitly, that would have lead a skilled artisan to believe that using the solid fats of Tsaur to produce the agar beads as taught by Delrieu would somehow result in irregular shaped particles.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605.

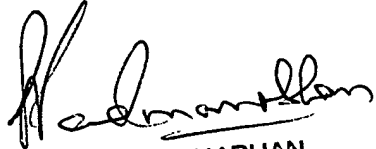
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The examiner can normally be reached on Monday through Friday, from 9:00AM until 6:30 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu  
Patent Examiner



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER